

April 19, 1999

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services,
rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

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CITIZEN PETITION

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act to request that the Commissioner of Food and Drugs require that the label of Mintezol be amended.

A. Action requested

The undersigned hereby requests that the Commissioner of Food and Drugs require that the "WARNINGS" section of the labeling of Mintezol shall contain the following text: "Mintezol use may cause threadworms (*Strongyloides stercoralis*) to migrate out of the user's body, thereby increasing the risk that the infection may be transmitted to other people."

B. Statement of grounds

A physician named Tony Dajer wrote an article titled "Triumph by Treachery." That article was published in the July 1994 issue of *Discover* magazine, pages 80-83. In that article, Dr. Dajer reported that when a patient in a New York hospital was found to be infected with threadworms (*Strongyloides stercoralis*) her physicians "clapped her in isolation and refused to touch her without gown and gloves." He also wrote that threadworm larvae can "be spread from feces to hands or sheets and then to other people."

In an article titled "Age-prevalence and household clustering of *Strongyloides stercoralis* infection in Jamaica" the authors of that article reported that the prevalence of threadworm infection "was highest among persons who shared a bedroom with a reference case." They asserted that this pattern of infection "is indicative of close contact transmission." This article was published in *Parasitology* (1995), volume 110, pages 97-102.

On November 1, 1990, Dr. Gregory Leo gave me a prescription for a seven-day course of Mintezol. I have attached a photocopy of that prescription. On the third night of taking that seven-day course of Mintezol many tiny worms started migrating out of my anus. They spread out over my buttocks and went up my back and down my legs. I got out of bed and showered. I called the Advice Nurse at Kaiser Hospital and asked if this should be happening. The Advice Nurse was not familiar with this side effect of Mintezol. I went back to bed. Shortly thereafter, more tiny worms began migrating out of my anus. I let them get further down my legs this time and then I got out of bed and showered again. I went back to bed and then a third army of worms migrated out of my anus. I let them get down to my feet this third time. They began "biting" me on the skin between my toes. After a dozen or so "bites" I realized that they were reinfecting me. I jumped out of bed and ran to the shower. I showered again and then I went back to bed and fell asleep. When I woke up in the morning it felt as though I had tiny worms squirming around here and there on my skin. I showered and dressed and then I changed the sheets on my bed.

The labeling of Mintezol states that, "Thiabendazole is vermifugal against *Ascaris lumbricoides* ('common roundworm'), *Strongyloides stercoralis* (threadworm), *Necator americanus* and *Ancylostoma duodenale* (hookworm), *Trichuris trichiura* (whipworm), *Ancylostoma braziliense* (dog and cat hookworm), *Toxocara canis* and *Toxocara cati* (ascaris), and *Enterobius vermicularis* (pinworm)." This statement does not clearly state that if a person ingests Mintezol then threadworms may migrate out of his or her body. Furthermore, this statement does not warn Mintezol users that such migration exposes other people to the risk of threadworm infection by "close contact transmission."

In summary, the physicians who "clapped" their patient in isolation were aware that threadworm infection can be transmitted from person to person by "close contact." Mintezol is "vermifugal" against *Strongyloides stercoralis*; in other words, Mintezol may cause threadworms to migrate out of a person's body. And such

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migrations can increase the risk that the threadworm infection may be transmitted to other people. The "WARNINGS" section of the labeling of Mintezol should therefore be amended to contain the following text: "Mintezol use may cause threadworms (*Strongyloides stercoralis*) to migrate out of the user's body, thereby increasing the risk that the infection may be transmitted to other people."

C. Environmental impact

This petition does not require the preparation of an environmental assessment because the action requested herein will not significantly affect the quality of the human environment. This petition is exempt under §25.34 of 21 CFR Ch. I.

D. Economic impact

Information about the economic impact of the action requested by this petition has not been requested by the Commissioner of Food and Drugs and, for that reason, such information is not included in this petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Scott G. Beach

Scott G. Beach
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Enclosed: Three additional copies of this petition.

KAISER FOUNDATION HOSPITAL PHARMACY
2025 MORSE AVENUE
SACRAMENTO, CALIFORNIA
REFILL RECORDER 973-6152 PHARMACY 973-3362

"KEEP ALL MEDICINES OUT OF REACH OF CHILDREN"

Caution: Federal law prohibits the transfer of this drug to any other person other than the patient for whom it was prescribed.

NO. **A504771** DR. LEO

THIABENDAZOLE 500mg/42

Take three tablets orally twice

daily for seven days

SCOTT BEACH 11/1/90db

REFILLS REMAINING none

DISCARD AFTER 11-43

CHEW THOROUGHLY BEFORE SWALLOWING

16 CHEWABLE TABLETS

MINTEZOL®

(THIABENDAZOLE, MSD)

00 mg CHEWABLE

No law prohibits dispensing without prescription

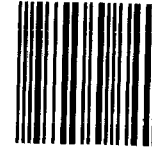
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